



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,939	09/12/2003	Frank A. Skraly	MBX 048	8379
23579 7590 05/01/2007 PATREA L. PABST PABST PATENT GROUP LLP 400 COLONY SQUARE, SUITE 1200 1201 PEACHTREE STREET ATLANTA, GA 30361			EXAMINER CHOWDHURY, IQBAL HOSSAIN	
			ART UNIT 1652	PAPER NUMBER
			MAIL DATE 05/01/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

10/661,939

Applicant(s)

SKRALY, FRANK A.

Examiner

Iqbal H. Chowdhury, Ph.D.

Art Unit

1652

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 29 March 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 5 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: 16-23.
Claim(s) withdrawn from consideration: 1-12, 24-35.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____.
13. ☐ Other: _____.

Continuation of 11. does NOT place the application in condition for allowance because: Previous rejection of Claims 16-23 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained. Claims 16-23 is directed to a recombinant organism comprising and expressing a heterologous gene encoding any CoA-dependent aldehyde dehydrogenase and any PHA synthase from any source for producing polyhydroxyalkanoates (PHAs). In addition, the microorganisms used in the method comprising the genus of any CoA-dependent aldehyde dehydrogenase and any PHA synthase is a very large genus having different structures. In the instant case claim 16 reads on a microorganism comprising any CoA-dependent aldehyde dehydrogenase and any PHA synthase i.e. there is no structural feature, which is representative of all the members of the heterologous CoA-dependent aldehyde dehydrogenase and PHA synthase recited in the claim. Many variants and mutant polypeptides with varied structure are encompassed by the recited genus. The specification teaches the structure of a single CoA-dependent aldehyde dehydrogenase isolated from *E. coli* and the structure of a single PHA synthase isolated from *Aeromonas caviae*, having the respective functional characteristics, which is insufficient to adequately describe the structure of required genus of heterologous CoA-dependent aldehyde dehydrogenase and PHA synthase having recited functional characteristics.

Previous rejection of Claims 16-23 under 35 U.S.C. 112, first paragraph, because the specification while being enabling for recombinant *E. coli* DH5 α comprising a plasmid expressing the CoA-dependent aldehyde dehydrogenase gene *eutE* from *E. coli* and PHA synthase from *Aeromonas caviae*, does not reasonably provide enablement for a recombinant organism comprising a plasmid having any CoA-dependent aldehyde dehydrogenase gene or any PHA synthase gene or any acyl-CoA transferase gene from any source.

The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the microorganism comprising extremely large number of aldehyde dehydrogenase gene (CoA-dependent), PHA synthase gene or acyl-CoA transferase gene broadly encompassed by the claims. The claims read on as organisms comprising mutants, variants or recombinants of any aldehyde dehydrogenase gene (CoA-dependent), any PHA synthase gene or acyl-CoA transferase gene. The disclosure is limited to a microorganism comprising the nucleotide and encoded amino acid sequences of only one aldehyde dehydrogenase gene (CoA-dependent), one acyl-CoA transferase gene or one acyl-CoA synthetase or one β -ketothiolase and one acetoacetyl-CoA reductase gene and three PHA synthase gene. Applicants have not, first of all provided a method of making all of the variants mutants of the *E. coli* CoA-dependent aldehyde dehydrogenase and PHA synthase. Second, they have not shown that any of the variants and mutants or recombinants of the above enzyme would successfully work in any organism including any bacteria, fungi, yeast, plant or animal to produce these enzymes. Without specific guidance, one of the of the ordinary skill in the art would have to test each and every one of aldehyde dehydrogenase gene (CoA-dependent), PHA synthase gene or acyl-CoA transferase gene to make a recombinant organism and test the same for producing polyhydroxyalkanoates (PHAs). Therefore, one of the ordinary skilled in the art would be subjected to undue experimentation to make and use the claimed invention.

Rebecca E. Prouty
REBECCA E. PROUTY
PRIMARY EXAMINER
GROUP-1800-
1602